OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

DEC 13 200

MEMORANDUM FOR SURGEON GENERAL OF THE ARMY
SURGEON GENERAL OF THE NAVY
SURGEON GENERAL OF THE AIR FORCE

SUBJECT: Quarantine of Frozen Blood Products to Reduce the Possible Transmission of West Nile Virus

The Centers for Disease Control and Prevention surveillance and epidemiologic data indicates that transfusions of red blood cells, platelets, and fresh frozen plasma have been implicated in 13 transfusion transmitted cases of West Nile Virus (WNV) infection. The current civilian and military inventory of fresh frozen plasma, cryoprecipitated antihemophilic factor, and frozen red blood cells includes units collected in 2002 in areas experiencing mosquito borne transmission of WNV to humans. Therefore, the American Association of Blood Banks, American Red Cross, Americas Blood Centers, and the Department of Defense consider it prudent to perform a "voluntary market withdrawal" of selected frozen transfusable in-date products in inventory in an effort to mitigate the risk of transmission of WNV through blood transfusion. The Food and Drug Administration believes that the voluntary withdrawal of certain frozen products is a rational response to the risk at this time.

The Armed Services Blood Program Office has coordinated and is issuing Blood Program Letter (BPL) 02-05, notifying the Services of the policy regarding the use of frozen blood products at risk for WNV. This policy directs the product management and prioritization for use of frozen products potentially at risk of transmitting WNV, in routine, emergency, and contingency situations.

This policy is effective immediately and should be communicated to appropriate commanders, health care providers, and others involved in its implementation.

The point of contact for this matter is COL G. Michael Fitzpatrick, MS, USA, Director Armed Services Blood Program Office, at DSN 761-8024 or (703) 681-8024, glen.fitzpatrick@otsg.amedd.army.mil.

Ellen P. Embrey
Deputy Assistant Secretary of Defense
(Force Health Protection and Readiness)

DEPARTMENT OF DEFENSE
ARMED SERVICES BLOOD PROGRAM OFFICE
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF

ASBPO (40-2b)

BPL 02-05
13 Dec 2002

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Policy for Product Management and Use of Frozen Products at Risk for Transmitting West Nile Virus (WNV)

1. The Armed Services Blood Program Office (ASBPO) was established by the Assistant Secretary of Defense for Health Affairs, (ASD [HA]), to coordinate the blood programs of the Military Services and the Unified Commands. In that respect, the ASBPO is issuing Blood Program Letter (BPL) 02-05, notifying the Services of the policy regarding the use of frozen products at risk for West Nile Virus (WNV). This policy directs the product management and prioritization for use of frozen products potentially at risk of transmitting WNV, in routine, emergency, and contingency situations.

2. Surveillance and epidemiological data from the Centers for Disease Control and Prevention (CDC) indicates that transfusions of red blood cells, platelets, and fresh frozen plasma have been implicated in 13 transfusion-transmitted cases of WNV infection. The current civilian and military inventory of Fresh Frozen Plasma (FFP), Cryoprecipitated Antihemophilic Factor (AHF), and Frozen Red Blood Cells (FRBCs) includes units collected in states experiencing mosquito borne transmission of WNV to humans in 2002. Therefore, in an effort to mitigate the risk of transmission of WNV through blood transfusion, the American Association of Blood Banks (AABB), American Red Cross (ARC), Americas Blood Centers (ABC), and the Department of Defense (DoD) consider it prudent to perform a "voluntary market withdrawal" of selected frozen transfusable in-date products in inventory. A joint statement, coordinated by the ARC, ABC, and the ASBPO was recently issued by the AABB recommending this withdrawal, *Statement of the American Association of Blood Banks, America's Blood Centers and the American Red Cross: Voluntary Withdrawal of Frozen Blood Products to Mitigate Risk of Transmission of West Nile Virus, 12 December 2002.* Surveillance data reported to the CDC indicates that the defined risk periods vary from state to state and were developed in consultation with the CDC. The FDA has been briefed and is fully aware of the actions being undertaken to implement the market withdrawal. The FDA issued a statement in support of the action and believes the withdrawal is a rational response to the risk at this time, *FDA Statement on Blood Industry's Voluntary Market Withdrawal of Certain Frozen Blood Products to Reduce Risk of West Nile Virus Transmission from Transfusion,* (Encl 1).

3. The ultimate goal of the withdrawal is to replace all affected frozen products that may pose a risk of WNV transmission, but that are not yet transfused. However, in light of the concerns about shortages of critical products and the potential for expanded contingency operations, frozen products affected by this withdrawal must be retained in current inventory until they can

be replaced through an accelerated inventory stock rotation program. Therefore, ASBPO is directing the quarantine of selected frozen products collected during defined risk periods, and a prioritized approach for the replacement and possible use of quarantined products until alternative products are available.

4. **Quarantine of Frozen Products Collected During the Defined Risk Period**: Blood donor centers, hospital transfusion services, Armed Services Whole Blood Processing Laboratories (ASWBPLs), blood supply units, blood transshipment centers, and other military medical units will:

a. **Upon receipt of Service implementation policy guidance, immediately quarantine all frozen products collected during the defined risk periods as listed in enclosure 2.**

1) This quarantine and withdrawal applies to homologous and rare frozen plasma and red cell products, currently in the blood donor center inventory AND those that have been shipped to or received from civilian organizations, Veterans Administration hospitals, other military treatment facilities (MTFs), ASWBPLs, and military medical units in support of contingency operations. It does not apply to autologous frozen products.

2) The defined risk periods are set at 7 days prior to the onset of symptoms of the first reported meningoencephalitis case in the state and ending with the 7th day after the onset of symptoms of the last reported case in the respective state. Product quarantine and withdrawal will include all frozen products collected during the defined risk periods in each respective state.

3) Blood donor centers collecting in multiple states must use a defined risk period that encompasses the earliest and latest dates for all the applicable states.

4) Product quarantine and withdrawal is not necessary for units collected outside the continental United States (OCONUS) or in the below listed states where no meningoencephalitis cases were reported. All other states are considered to have periods of risk for transmission of human WNV for 2002.

Alaska	Hawaii	New Hampshire	Utah
Arizona	Idaho	New Mexico	Washington
California	Maine	Oregon	Wyoming
Delaware	Nevada	Puerto Rico	

5) Quarantined products must be maintained in a quarantined (QRA) status in the Defense Blood Standard System (DBSS), if available, and should be physically segregated from the rest of the available inventory to prevent unauthorized release. As a minimum requirement, the frozen storage area must be specifically identified as a quarantine area. When changing the status of these units from available (AVL) to quarantined (QRA) in DBSS, a comment

should be placed in the product comment field to indicate the product was quarantined for potential risk of WNV.

6) At military medical units where DBSS is not available for inventory management, the units must be physically segregated from the rest of the available inventory and should be tagged or labeled as quarantined to prevent unauthorized release. As a minimum requirement, the frozen storage area must be specifically identified as a quarantine area.

7) Homologous frozen red blood cell units, collected during the defined risk period, as part of the ASBPO frozen blood replacement plan, will continue to be held in a quarantine status and will not be destroyed. After a test for WNV has been developed, a determination will be made as to stored sample testing requirements and suitability for release of these products.

8) Homologous rare frozen products, collected during the defined risk period will continue to be held in a quarantine status and will not be destroyed. Transfusion of these products will be handled in accordance with existing Service and local protocols for emergency release and the additional requirements for release of quarantined products as detailed in paragraphs 6 and 7 of this document.

b. **Notify customers/consignees of the requirement to quarantine products that were collected in the defined risk period and document notification.**

1) Consignee notification will include the applicable defined risk period(s), including the peak incidence week(s), as defined in enclosure 2, the type of product involved, the shipment date, and the expiration dates of the products involved.

2) Documentation of consignee notification must include the date, time, and name of the person making and receiving the notification. In a voluntary market withdrawal, the collection and/or shipping facility is not required to obtain the final disposition of shipped products.

3) If a consignee has subsequently shipped the product, it is the consignee's responsibility to notify the subsequent receiving facility of the requirement to quarantine the products and to relay documentation of the subsequent notification to the originating facility. Notification to the consignee must include instructions that clearly delineate the consignee responsibility for subsequent consignee notification.

5. **Replacement of Quarantined Frozen Plasma Products:** As soon as feasible, and consistent with the need to maintain inventories critical for patient care and operational requirements, Services will give priority to replacing units collected during peak incidence weeks of West Nile associated meningoencephalitis cases, followed by replacement of units collected during weeks prior to and subsequent to peak weeks.

a. Services must immediately accelerate production of FFP and CRYO and develop plans to replace quarantined plasma products within their respective Service and, to the greatest extent possible, assist other Service blood programs with replacement of quarantine products.

b. Service plans must include identification of Service blood donor centers that will make and stockpile frozen plasma components during non-endemic months in order to eliminate the need to make these products during anticipated future defined risk periods, until such time as a licensed test for WNV or other intervention (including testing under IND) is introduced.

c. This withdrawal may precipitate a shortage of FFP; therefore, Services must ensure that the inventory of PLASMA Cryoprecipitated AHF Removed (Component Product Code 18401) is also increased in conjunction with the production of CRYO for use by refractory patients with Thrombotic Thrombocytopenia Purpura (TTP).

d. Services must ensure that ASWBPL FFP shipment quotas are maintained at required levels and that no quarantined products, collected during the defined risk period(s), are shipped to the ASWBPLs.

6. **Prioritization for Use of Quarantined Products:** To the extent that quarantined products must be transfused during the replacement time period due to medical need, transfusion services and military medical units are strongly advised to manage inventories in a manner that avoids transfusion of blood products collected during the defined risk period, specifically to patients at greater risk for transfusion related WNV infection.

a. If it becomes necessary to transfuse quarantined products, they should be used only at the discretion of the attending physician and/or the command surgeon. *The Clinical Guidelines for Transfusing Quarantined Frozen Products at Risk for WNV*, (Encl 3), shall be used in determining the medical conditions of high risk patients and in accessing the risks associated with transfusing quarantined products. These products should only be considered for transfusion to other patients when inventories of non-quarantined products are low and/or product availability is limited. Service or local policies should be developed to ensure the safest blood possible is issued and transfused on a case-by-case basis when inventories of non-quarantined products are low. **Quarantined products should be used in the following order of priority:**

1) Units collected outside the defined risk period should be considered as the first line inventory for transfusion support to all patients. To the greatest extent possible, these units should be specifically reserved for transfusion support to high-risk recipients, as identified in enclosure 3.

2) Units collected within the defined risk period, but as near as possible to the beginning and/or the end of the defined risk period, should be used as the second line inventory in the transfusion support for all patients. To the greatest extent possible, they should NOT be used for transfusion support to high-risk recipients, as identified in enclosure 3.

3) Units collected within the defined risk period, but during weeks of peak incidence of West Nile associated meningoencephalitis cases, should be used as the last line inventory for transfusion support to all patients. These units should NOT be used for transfusion support to high-risk recipients identified in enclosure 3. Peak incidence weeks of highest WNV activity in each state are listed in enclosure 2.

7. **Documentation of Release of Quarantined Products**:

a. If the decision to release quarantined blood products, collected during the defined risk period, is made at a level below the Unified Command Surgeon or the Joint Task Force (JTF) Surgeon, documentation of the need to use the product(s) will be generated at the local medical treatment facility (MTF) for each transfused patient, in accordance with Service and local policies and procedures. MTFs should obtain and document specific written authorization from the patient's attending physician and should maintain this information for inspection by accrediting, licensing, and legal organizations.

b. If a Unified Command or JTF Surgeon determines that the release of quarantined blood products collected during the defined risk period is warranted, individual patient documentation at the MTF level is not required. The Unified Command or JTF Surgeon will forward authorization to release the blood products to the ASBPO and applicable blood program facilities, prior to product release. Written authorization must:

Explain the nature of the situation requiring release of quarantined products.

2) Provide authorization to the Blood Product Depots (BPD), Blood Transshipment Centers (BTC), Transportable Blood Transshipment Center (TBTC), Blood Supply Units (BSU), and Medical Treatment Facilities (MTF) to remove quarantined units from inventory, and to subsequently ship, thaw, and/or transfuse the products.

3) Instruct the transfusing facilities to maintain records of the patients receiving these plasma products.

8. To the extent possible, Services will make every effort to ensure adequate supplies of frozen products, with lesser or no ascertainable risk, are provided to areas where frozen products are at higher risk for WNV transmission through transfusion. Under existing regulations, withdrawn plasma prepared from collections of whole blood may be relabeled as recovered plasma. Blood donor centers with existing short supply agreements may continue to ship recovered plasma for further manufacture under their existing agreements, provided that temperature storage requirements are met. However, blood donor centers that wish to convert frozen plasma, collected by apheresis during defined risk periods, to recovered plasma prior to the frozen plasma outdate, must request a variance from the FDA. It is expected that cryoprecipitate, and frozen plasma converted to recovered plasma, that cannot be shipped for further manufacture under existing agreements, will be destroyed as soon as replacement inventory is available.

SUBJECT: Policy for Product Management and Use of Frozen Products at Risk for Transmitting West Nile Virus (WNV)

Quarantined plasma products should not be shipped back to the manufacturer unless specifically requested by the manufacturer for preparation of recovered plasma.

9. This policy must be incorporated in OPLANS, CONPLANS and Service regulations as soon as possible. **Service Blood Program Officers and Combatant Command Joint Blood Program Officers** must complete the enclosed form, *Acknowledgment of Receipt and Implementation*, (Encl 4), and return the signed original or fax copy to the ASBPO NLT 30 December 2002. A copy of all Service and Unified Command implementing policy documents must also be forwarded to the ASBPO within 30 days of implementation. Commander B.G. Bartley, MSC, USN is the Armed Services Blood Program Office point of contact for this action and can be reached at DSN 761-8024/1736, (703) 681-8024/1736 or via e-mail at brenda.bartley@otsg.amedd.army.mil.

G. Michael Fitzpatrick

Encl 1-4
As stated

G. MICHAEL FITZPATRICK
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Director

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ASBPO (40-2b) BPL 02-05
SUBJECT: Policy for Product Management and Use of Frozen Products at Risk for Transmitting West Nile Virus (WNV)

STATEMENT Media Inquiries: 301-827-6242

December 12, 2002 Consumer Inquiries: 888-INFO-FDA

FDA STATEMENT ON BLOOD INDUSTRY'S VOLUNTARY MARKET WITHDRAWAL OF CERTAIN FROZEN BLOOD PRODUCTS TO REDUCE RISK OF WEST NILE VIRUS TRANSMISSION FROM TRANSFUSION

The Food and Drug Administration (FDA) has been working with the Centers for Disease Control and Prevention (CDC) and the blood banking community to assess and manage the potential risk of West Nile Virus transmission from blood and blood products.

A small number of cases of West Nile Virus infection have been linked to the receipt of blood products that carried the virus. The estimated risk to recipients of blood and blood products is thought to be low; but it varies by region and time period of the epidemic.

In October 2002, FDA issued a final guidance document that provided recommendations for the assessment of donor suitability and blood and blood product safety in cases of known or suspected West Nile Virus infection (www.fda.gov/cber/gdlns/wnvguid.pdf).

Although the risk from an individual unit of blood or plasma collected and frozen during the epidemic is likely to be low, FDA believes that the voluntary withdrawal of certain frozen products is a rational response to the risk at this time.

FDA will continue to review its recommendations as we learn more about the epidemic. As in many situations involving potential risks from blood products, it is important to weigh the public health benefits of possible interventions to ensure that an adequate supply of blood products is available. FDA is pledged to working with CDC and the blood banking community to help ensure that safe products will be available wherever they are needed.

FDA will provide updates to this situation as new information becomes available

Enclosure

SUBJECT: Policy for Product Management and Use of Frozen Products at Risk for Transmitting West Nile Virus (WNV)

Table 1:

Human WNV Cases with Meningoencephalitis by State: Date of Earliest and Latest Case

Source: CDC, 12/10/02

Explanations:

The table contains the date of onset of earliest and the latest case of meningoencephalitis.

The list of "seven days before and seven days after" is a safety margin added to the withdrawal.
The peak weeks were selected from incidence tables - they represent periods of highest activity in the state; some selections were arbitrary because of continuous activity or low number of cases.

There were cases reported every week between the earliest and the latest case in all states with WNV activity

					Total number	Calendar	Peak Week(s)		
State	Earliest Case	Latest Case	7 Days Before	7 Days After	of Days	Week #	Week of	To	Week of
Alabama	15-Jul	12-Oct	8-Jul	19-Oct	103	33, 36	11-Aug		1-Sep
Arkansas	29-Jul	21-Sep	22-Jul	28-Sep	68	32	4-Aug		
Colorado	12-Sep	9-Oct	5-Sep	16-Oct	41	37-41	8-Sep		6-Oct
Connecticut	23-Aug	6-Oct	16-Aug	13-Oct	58	36	1-Sep		
Dist. of Columbia	19-May	8-Sep	12-May	15-Sep	126	31	28-Jul		
Florida	13-Jul	12-Nov	6-Jul	19-Nov	136	39,40	22-Sep		29-Sep
Georgia	29-Jul	17-Oct	22-Jul	24-Oct	94	34,35	18-Aug		25-Aug
Illinois	10-Jul	13-Oct	3-Jul	20-Oct	109	33-37	11-Aug		8-Sep
Indiana	27-Jul	3-Oct	20-Jul	10-Oct	82	35-37	25-Aug		8-Sep
Iowa	23-Aug	28-Oct	16-Aug	4-Nov	80	37-38	8-Sep		15-Sep
Kansas	7-Aug	28-Sep	31-Jul	5-Oct	66	32-39	4-Aug		22-Sep
Kentucky	3-Aug	21-Oct	27-Jul	28-Oct	93	34-37	18-Aug		8-Sep
Louisiana	10-Jun	16-Oct	3-Jun	23-Oct	142	29-33	14-Jul		11-Aug
Maryland	27-Jul	4-Oct	20-Jul	11-Oct	83	33-34	11-Aug		18-Aug
Massachusetts	2-Aug	5-Oct	26-Jul	12-Oct	78	35	25-Aug		
Michigan	20-Jul	25-Oct	13-Jul	1-Nov	111	33-38	11-Aug		15-Sep
Minnesota	15-Aug	23-Sep	8-Aug	30-Sep	53	35	25-Aug		
Mississippi	24-Jun	19-Oct	17-Jun	26-Oct	131	30-35	21-Jul		25-Aug
Missouri	31-Jul	25-Aug	24-Jul	1-Sep	39	32	4-Aug		
Montana	14-Sep	14-Sep	7-Sep	21-Sep	14	37	8-Sep		
Nebraska	2-Aug	30-Sep	26-Jul	7-Oct	73	36-38	1-Sep		15-Sep
New Jersey	20-Aug	4-Oct	13-Aug	11-Oct	59	36	1-Sep		
New York	20-Jul	20-Oct	13-Jul	27-Oct	106	36	1-Sep		
North Carolina	1-Sep	20-Sep	25-Aug	27-Sep	33	36-38	1-Sep		15-Sep
North Dakota	22-Aug	7-Sep	15-Aug	14-Sep	30	34	18-Aug		
Ohio	27-Jul	13-Oct	20-Jul	20-Oct	92	34-36	18-Aug		1-Sep
Oklahoma	19-Jul	8-Oct	12-Jul	15-Oct	95	38-40	15-Sep		29-Sep
Pennsylvania	3-Aug	12-Oct	27-Jul	19-Oct	84	34-39	18-Aug		22-Sep
Rhode Island	14-Sep	14-Sep	7-Sep	21-Sep	14	37	8-Sep		

SUBJECT: Policy for Product Management and Use of Frozen Products at Risk for Transmitting West Nile Virus (WNV)

State	Earliest Case	Latest Case	7 Days Before	7 Days After	Total number of Days	Calendar Week #	Peak Week(s) Week of	To	Week of
South Carolina	26-Jul	26-Jul	19-Jul	2-Aug	14	30	21-Jul		
South Dakota	28-Jul	2-Oct	21-Jul	9-Oct	80	35	25-Aug		
Tennessee	22-Jul	22-Sep	15-Jul	29-Sep	76	34-35	18-Aug		25-Aug
Texas	3-Jul	24-Nov	26-Jun	1-Dec	158	32-34	4-Aug		18-Aug
Vermont	26-Aug	26-Aug	19-Aug	2-Sep	14	35	25-Aug		
Virginia	20-Jul	19-Sep	13-Jul	26-Sep	75	34	18-Aug		
West Virginia	18-Aug	18-Aug	11-Aug	25-Aug	14	34	18-Aug		
Wisconsin	24-Jul	11-Oct	17-Jul	18-Oct	93	36-38	1-Sep		15-Sep

Clinical Guidelines
For Transfusing Quarantined Frozen Products to Patients at Risk for Transfusion Transmitted West Nile Virus (WNV)

Background:

Since December 3, 2002, 3775 cases of WNV infection have been reported with 216 deaths, of which only three were related to blood transfusion. As of December 10, 2002 only 13 persons have been identified who acquired WNV infection from infected blood components from eight donors. These eight donors resided in states where mosquito-borne WNV infections to humans were documented by surveillance during the 2002 WNV epidemic. Transfusions of red blood cells, platelets, and fresh frozen plasma have been implicated. Persons with transfusion associated WNV infection were ages 7 to 75 years (median 47 years). Four persons had hematological or other advanced malignancies; three had stem cell or organ transplantation; and four persons (all 70 years or older) received transfusions associated with other medical problems or a surgical procedure. In addition, transfusion-related infection was documented in two women who received transfusions post-partum. Transmission to a breast-feeding infant from one of these women was documented. Nine patients developed WNV meningoencephalitis and three died.

High Risk Recipients:

When transfusion of quarantined frozen products to high-risk recipients is indicated, the benefits should outweigh the risks and other alternatives should not be available. Overall, the risk of clinically significant WNV transmission from transfusion of blood products is very low. In general, patients may be considered at risk for developing severe WNV disease (meningoencephalitis) in a manner similar to the evaluation of risk for other transfusion-transmitted viral infections and include the very young, the elderly, some cancer patients, and the chronically ill. Patients at highest risk for severe WNV disease are listed below and, to the greatest extent possible, should not be transfused with frozen products collected during the entire defined risk period for each relevant state:

- Immunocompromised patients: (Particularly organ and stem cell transplant recipients, patients on immunosuppressive drugs, patients with hematological malignancies and myelodysplasias, and patients with other advanced malignancies).
- Patients over 65 years of age and neonates.
- Pregnant, immediate post-partum, and breastfeeding women.

The above risk groups are not inclusive, but are based on medical conditions associated with immunosuppression and medical conditions associated with known cases of West Nile meningoencephalitis. The risks of WNV infection for adult recipients <50 years old, who are not ill or specifically immunocompromised, are generally perceived to be low.

- Nationwide it is estimated that there may be 1-2 infections per 10,000 donations
- Endemic areas are estimated to have risks as high as 16 infections per 10,000 donations
- One in 150 WNV infections progress to WNV meningoencephalitis

Suspected Cases Of Transfusion Related WNV Transmission

If a transfusion recipient is suspected to have acquired WNV from a blood component, the standard transfusion reaction workup procedures should be followed. To assist in identification of other possible cases of WNV infection potentially associated with transfusion, the FDA requires that patients diagnosed with WNV infection, who received blood transfusions or organs within the 4 weeks preceding the onset of symptoms, should be reported to the CDC through local public health authorities and to Service headquarters through the local chain of command. Serum or tissue samples should be retained for later studies. A patient lookback should be initiated to identify potentially associated donors and additional product quarantine and retrieval performed as required in ASBPO BPL 02-03, 27 November 2002.

Cases of diagnosed WNV infection in donors who had onset of symptoms within 2 weeks of blood donation must be reported to the CDC through state and local public health departments and to Service headquarters through the local chain of command, as required in ASBPO BPL 02-03, 27 November 2002.

Additionally, if a suspect donation results in the fatality in a transfusion recipient, facilities must report the fatality to the FDA, through the respective chain of command and Service Blood Program Office as required in ASBPO BPL 02-03, 27 November 2002.

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ACKNOWLEDGMENT OF RECEIPT AND IMPLEMENTATION

Service Blood Program Officers and Combatant Command JBPOs only: Complete this Acknowledgment of Receipt and Implementation and retain one copy in your file. Return the signed original or fax copy to the Armed Services Blood Program Office

NLT 30 December 2002

BPL 02-05
Policy for Product Management and Use of Frozen Products at Risk for West Nile Virus (WNV)
13 December 2002

The document listed above was received and the policy implemented by:

SERVICE/UNIFIED COMMAND:_____

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